UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	
v.	**Criminal No: 09-CR-10330-GAO**
(1) STRYKER BIOTECH, LLC, **(2) MARK PHILIP,** **(3) WILLIAM HEPPNER,** **(4) DAVID ARD and** **(5) JEFFREY WHITAKER,**	
Defendants.	

DEFENDANTS' TRIAL BRIEF

Defendants Stryker Biotech LLC ("Biotech"), Mark Philip, William Heppner, Jeffrey Whitaker, and David Ard (the "Individual Defendants") (collectively, the "Defendants") submit this Trial Brief to outline for the Court the key legal, factual, and logistical issues pertaining to the trial in this matter. This Trial Brief provides a short summary of the case, followed by a discussion of how each of the Defendants' outstanding motions, including the motions *in limine* filed on December 7, 2011, intersects with the key trial issues.

I. The Charges

As the Government has stated repeatedly, this is a fraud case. The first twelve counts of the Superseding Indictment all allege a variation of fraud arising out of the manner in which the Defendants allegedly promoted the use of Biotech's OP-1 bone growth products ("OP-1") with Calstrux, a bone void filler also manufactured by Biotech.[1] The crux of this case is whether the

[1] The Superseding Indictment charges all five defendants with a dual-prong conspiracy to commit wire fraud and to defraud the United States (Count 1) and five substantive wire fraud counts (Counts 2-5). Stryker Biotech is charged

Defendants engaged in the "deliberate manipulation of physicians into using an unapproved and untested mixture of OP-1 and Calstrux that was associated with serious adverse events." Superseding Indictment at ¶ 57. Defendants vigorously dispute the Government's fraud allegations and the Government's assertion that the use of Calstrux in conjunction with OP-1 by surgeons was "associated with serious adverse events" or was otherwise unsafe.

II. Factual & Legal Background

There are certain baseline factual and legal issues that are critical to the jury's assessment of these fraud charges. First, for decades, the surgeons who perform the types of complicated spinal and orthopedic surgeries that are at issue in this case have used a combination or "mix" of natural and synthetic products to achieve bone growth in spinal fusions for compromised patients. Historically, that often meant mixing bone harvested from a patient's iliac crest (hip) bone with extenders such as local bone, cadaver bone chips, synthetic bone void fillers, or a variety of other products designed to serve as a "scaffold" for the growth of new bone in spinal fusions or severe fractures. Over the years, surgeons mixed bone morphogenetic proteins ("BMPs"), like OP-1, with literally dozens of different carriers or extenders. Defense expert William Caton will testify that the "mixing of products is standard-of-care practice in spinal surgery" and that "iliac crest, bone marrow aspirate, and BMPs can be mixed with local bone, cadaveric bone, blood, saline, bone void fillers, or a number of other bone expander products." *See* Excerpt from William Caton Expert Disclosure provided to the Government on November 9, 2010.

Understanding this ingrained, long-standing clinical practice is critical to the question of whether the Defendants conspired to defraud doctors by discussing with surgeons the concept of

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with six counts of misbranding with the intent to defraud or mislead (Counts 7-12). Stryker Biotech is also charged with one count of making a false statement to the FDA (Count 13), which Defendants contend should be severed.

mixing OP-1 with extenders like Calstrux, particularly in light of the fact that the FDA, when evaluating the product for clearance, deemed Calstrux to be "substantially equivalent" to several other bone void fillers that surgeons had already been using for years.

Second, the Government is prosecuting this fraud case as if proof of off-label promotion is equivalent to proof of fraud, which it most certainly is not. The Government should not be allowed to conflate the two. As to the Government's contention about off-label use, a legal principle central to the defense of this case is that surgeons are legally permitted to use FDA-approved products in an "off-label" manner when they decide that such use is in the best interests of their patients. This is federal law. *See* 21 U.S.C. § 396 (FDCA does not "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship"); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349-51 & n.5 (2001). Yet, at the same time, the FDA has established a complex web of rules and regulations that purport to ban the "promotion" of off-label uses by manufacturers. The result is a counter-intuitive dichotomy in the law that colors every interaction a Biotech sales representative may have had with a surgeon: the surgeon may have wanted to use OP-1 and Calstrux in a manner that, while consistent with the standard of care, a sales representative could not affirmatively "promote." In fact, it is well-established that BMPs are often not used in strict accordance with their FDA-approved labels. This is because, in this rapidly advancing area of medicine, surgeons bring their professional judgment and clinical experience to bear when deciding to use BMPs and extenders together—outside the products' labeled indications—in order to obtain optimal patient outcomes. The Biotech sales representatives who assisted surgeons in this process believed, in

good faith, that they were supporting the surgeons' legal prerogative to use BMPs "off label" and that they never deceived them into mixing BMPs with extenders.

III. Outstanding Motions Pertaining to the Counts to Be Tried on January 4, 2012

There are three pending motions that pertain directly to the critical issue of which counts in the Superseding Indictment will be presented to the jury at this trial. Each of these motions should be granted for the reasons stated therein and because dismissing these counts would greatly streamline the evidence and shorten this trial.

A. Motions to Sever Count 13:

The Defendants seek severance of the false statement charge because it alleges an entirely different course of conduct from the rest of the Superseding Indictment and therefore was not properly joined under Rule 8. The Defendants have also moved for severance of this count under Rule 14 on the grounds that it is unduly prejudicial.[2]

- Defendants William Heppner, David Ard and Jeffery Whitaker's Motion to Sever Count Fifteen Due to Misjoinder Under Federal Rule of Criminal Procedure 8(b) [Dkt. #'s 132, 133, 144, 160, 162, and 163]
- Defendant Stryker Biotech's Motion to Sever Count 15 [Dkt. #'s 135, 136, 144, 160, 162, and 163]
- Defendant Mark Philip's Motion to Sever Count 15 [Dkt. # 137, 144, 160, 162, and 163]

B. Motion to Dismiss Count 13:

Biotech seeks dismissal of this count because the Government's collective intent theory underlying this false statement charge is legally insufficient as a matter of law.

- Defendant Stryker Biotech, LLC's Motion to Dismiss Count 13 [Dkt. #'s 168, 169, 172, and 203]

[2] For the reasons stated in their Reply Brief in Support of the Motion to Sever [Dkt. # 160, at 13, n.9], the Defendants also request that the court exclude and strike, under Rule 404(b), evidence pertaining to the false statement count that has been added to the conspiracy's manner and means description in the Superseding Indictment.

C. Motion to Reconsider the Motion to Dismiss Counts 7-12 for Lack of Venue:

The Government failed to cure the venue defects inherent in its original misbranding counts when it superseded the original Indictment, though it limited the defendants in the misbranding counts to just Biotech in the Superseding Indictment. Nonetheless, the alleged acts at issue in Counts 7-12 still took place hundreds and, in some cases, thousands of miles outside this district. The Government's inability to address the venue deficiencies demonstrates that it has no evidence to offer at trial to connect these specific sales representative-surgeon interactions with any conduct occurring in the District of Massachusetts. Dismissal of the misbranding charges would also greatly simplify the legal concepts that the jury will be asked to decide and shorten this trial.

- Defendant Stryker Biotech's Renewed Motion and Memorandum of Law to Dismiss Misbranding Counts for Lack of Venue [Dkt. #'s 87, 88, 103, 112, and 182]

IV. Renewed Motions to Dismiss

A. Motion to Dismiss the Conspiracy to Defraud the FDA Charge:

Defendants have renewed their motion to dismiss the portion of the conspiracy count (Count 1) that charges them with conspiring to impair, impede, and obstruct the FDA's lawful regulatory functions through craft, trickery, and deceit. The Superseding Indictment describes the objective of the conspiracy as having been accomplished through "illegal off-label promotion" and deceiving surgeons by providing them with false and misleading information. As Defendants previously argued, those allegations do not sufficiently describe a conspiracy to defraud the FDA. The Government previously has assured the Court that it is not attempting to shoehorn allegations of intentional off-label promotion (a misdemeanor offense) into a charge of conspiracy to defraud the FDA (a felony offense). At a minimum, Defendants ask this Court to

provide some clarity as to just what the Government must prove to convict them of the conspiracy to defraud the FDA charge. Defendants are entitled to know what they are defending against, and the Government's allegations are far from clear.

- Defendants' Motion to Dismiss Count 6's Charge of Conspiracy to Defraud the United States [Dkt. #'s 85, 86, 99, 114, and 194]

B. Other Motions to Dismiss Denied Without Prejudice:

The following other previously filed motions were denied by the Court without prejudice, and were renewed by the Defendants following the return of the Superseding Indictment:

- Defendants' Motion to Dismiss Counts Seven Through Fourteen of the Indictment on First Amendment Grounds [Dkt. #'s 65, 66, 72, 104, and 194]
- Defendants' Motion to Dismiss Counts 7-14 and the "Offense" Prong of Count 6 on Due Process and Statutory Construction Grounds [Dkt. #'s 81, 82, 101, 113, and 194]
- Defendants' Motion to Dismiss Counts 2 and 3 of the Indictment for Lack of Venue [Dkt. #'s 83, 84, 103, 112, and 194] applicable to Superseding Indictment Counts 4 and 5.[3]

V. Outstanding Motions Pertaining to the Fraud Allegations

Several of the outstanding motions challenge the legal underpinnings of the Government's fraud theory in this case.

A. Fraud by Omission – Request for a Preliminary Jury Instruction:

As is evident from the Superseding Indictment, the Government's fraud theory is grounded in non-disclosures, or alleged fraud based on what the Defendants and sales representatives supposedly did *not* tell surgeons. This is a legally tenuous theory that applies only in those limited circumstances that the Defendants identified in their Motion for a Preliminary Jury Instruction. Defendants fully expect Government witnesses will be asked some

[3] Defendants David Ard and Jeffery Whitaker's Motion to Dismiss Counts Thirteen and Fourteen for Failure to State an Offense was also dismissed without prejudice but is now moot, because the Government has dropped those counts in the Superseding Indictment. [Dkt. #'s 79, 80, 100, and 111].

variant of the following: "would you have liked to have known [fact x]." This question is improper in the absence of the Government proving that the speaker had some duty to provide the information at issue. The Defendants will object to these types of questions at trial, because such questions, and the answers provided, could lead the jury to conclude that fraud has been established simply because information was not disclosed in a specific conversation. Yet, as the Defendants briefed, the First Circuit has held that non-disclosures of information can possibly constitute fraud only if, among other things, they are accompanied by either (a) a duty to provide the information, or (b) the active concealment of the information with an intent to deceive. *Bonilla v. Volvo Car Corp.*, 150 F.3d 62, 69-70 (1st Cir. 1998). For these reasons, it is essential that the Court provide a pre-trial jury instruction on the fraud by omission theory that permeates the Government's entire case.

- Motion and Memorandum of Law in Support of Defendants' Request for Preliminary Jury Instruction Regarding Fraud by Omission [Dkt. # 185]

B. Fraud by Omission – Adverse Events:

Allegations that patients treated with the OP-1/Calstrux mixture experienced "adverse events" are provocative and, if admitted, will color the jury's perspective of this entire case. The following two motions *in limine* challenge the admissibility of (1) evidence of "adverse events" experienced by patients treated with Calstrux and OP-1, and (2) in-court testimony or out-of-court statements, whether by "experts" or lay witnesses, that suggest or insinuate the existence of a causal link between "adverse events" and the surgeon's decision to use Calstrux as an adjunct to OP-1:

- Defendants' Motion *In Limine* and Memorandum of Law To Exclude Evidence of Anecdotal Adverse Event Reports and Strike the Allegation that Defendants Defrauded Surgeons by Failing To Disclose Adverse Events [Dkt. # 191]

- Defendants' Motion *In Limine* and Supporting Memorandum of Law To Exclude Expert and Lay Witness Testimony as to the Cause of "Adverse Events" [Dkt. # 188]

C. Fraud by Misrepresentation:

There are very few specific alleged misrepresentations—as opposed to supposed omissions—in the Superseding Indictment. One of the few affirmative misrepresentations alleged pertains to supposed statements about OP-1's Humanitarian Device Exemption approval and the representation that surgeons could use OP-1 off-label like any other approved device. This statement was legally accurate and the Defendants have moved to strike this allegation from the Superseding Indictment.

- Defendants' Motion *Limine* and Memorandum of Law to Strike Paragraph 58(e)(2) of the Superseding Indictment [Dkt. # 189]

VI. Motion to Exclude the March 1, 2006 Legal Consequences Slide and To Preclude the Government from Conflating "Off-Label Promotion" with Fraud

Federal courts, including courts in this District, have made clear that "off-label promotion" is not the equivalent of criminal fraud. Defendants are concerned that the Government may use certain evidence to improperly and prejudicially suggest otherwise. Consistent with this concern, Defendants have specifically challenged the admissibility of one particular PowerPoint slide allegedly presented by John Houghton, a former Biotech Vice President, during a March 1, 2006 teleconference with the Biotech sales force. This slide discussed the legal consequences of off-label promotion, including the prospect of a criminal misbranding prosecution. This particular motion is essential to the Defendants' receiving a fair trial on the fraud charges in the Superseding Indictment. This slide is a linchpin of the Government's case, as Defendants expect the Government will argue that as a result of this presentation, every Defendant was advised that the promotion of a mixture of Calstrux and OP-1

was illegal. If the Defendants engaged in such promotion after this March 1, 2006 presentation, the Government will contend that the Defendants are guilty of the crimes charged in the Superseding Indictment. Nothing could be further from the truth, however, since the fraud laws the Defendants are accused of violating in this Superseding Indictment were not addressed in this PowerPoint presentation. Allowing the jury to be exposed to this irrelevant and prejudicial evidence of "what the law is" would deny the Defendants a fair trial.

- Defendants' Motion *In Limine* and Memorandum of Law To Exclude One Slide Contained in a March 1, 2006 PowerPoint Presentation, and for a Cautionary Instruction [Dkt. # 192]

VII. Motions Pertaining to Government Cooperators

Central to the Government's fraud case will be the testimony of four former Biotech sales representatives who were caught by Biotech forging hospital documentation, terminated by the company, and investigated by the Department of Justice. They each received a sweetheart deal from the Government in exchange for pleading guilty to felony misbranding. Their credibility will be a key issue at trial. There are two very important motions outstanding that go to the testimony of the four pleaders and the Defendants' access to key impeachment information in the Government's possession:

- Defendants' Motion *In Limine* and Memorandum of Law to Limit the Government's Use of the Felony Misbranding Pleas of Darnell Martin, Justin Demming, Shane Doyle, and Christopher Ring [Dkt. # 186]
- Motion to Compel Disclosure of Exculpatory Information Relating to the Government's Four Cooperating Witnesses [Dkt. # 152]

VIII. Motions to Strike Specific Allegations in the Superseding Indictment

Two of the pending motions are aimed at prohibiting the Government from referencing certain erroneous legal concepts before the jury. Specifically, the Superseding Indictment makes several references to a legal "cap" on the number of patients who could be treated annually with

the OP-1 products. No such cap exists under the law, and the Government's persistence in arguing that the Defendants exceeded a legally imposed ceiling is erroneous and unduly prejudicial. Similarly, the Superseding Indictment makes repeated references to "illegal off-label" promotion, despite the fact that (1) the Department of Justice has taken the position that promotion of an FDA-approved product for an unapproved use is not, in and of itself, unlawful, and (2) federal courts have consistently recognized that "off-label promotion" is not the equivalent of criminal fraud.

- Defendants' Motion *In Limine* and Memorandum of Law To Exclude Reference to an HDE "Cap" and To Strike Paragraphs 49, 50, and 58(J) [Dkt. # 184]
- Defendants' Motion *In Limine* and Memorandum of Law To Exclude Evidence and Argument Concerning "Illegal" Off-Label Promotion and To Strike Paragraphs 44 and 57 [Dkt. # 183]

IX. Motions Pertaining to Limiting Government Expert Testimony

The Defendants have one motion outstanding to limit the ability of the proposed expert FDA witnesses to testify on the biological effect of combining OP-1 and Calstrux because they lack sufficient clinical or medical expertise to opine on this topic.

- Defendants' Motion *In Limine* and Supporting Memorandum of Law To Exclude Certain Testimony of FDA Witnesses Aric Kaiser and Erin Keith [Dkt. #'s 187 and 190]

X. Motions Pertaining to Specific Evidence

Several pending motions are directed at discrete pieces of evidence the Defendants contend are not admissible under Rule 401, 403 or both. These motions are as follows:

- Defendants' Motion-in-Limine to Preclude the Government from Referring to Heterotopic Ossification as a "Tail," "Growing a Tail," or any Similar Variation [Dkt. #'s 176 and 177]
- Defendants' Motion *In Limine* and Memorandum of Law To Exclude Evidence of the Sale of Assets by Defendant Stryker Biotech to Olympus Biotech [Dkt. # 178]

- Defendants' Motion *In Limine* and Memorandum of Law To Exclude Evidence of the Decision to Discontinue Calstrux and Remove the Product from the Market [Dkt. # 180]
- Defendants' Motion *In Limine* To Exclude Evidence of Mark Philip's Separation from Stryker Biotech [Dkt. #'s 174 and 175]

In light of the documents contained in the Government's December 13, 2011 exhibit list, the Defendants anticipate that a limited number of additional motions *in limine* directed at specific evidence will also be necessary.

XI. Exclusion of Inadmissible "Other Bad Acts" Evidence

The Government has told Defendants that, in its view, any interactions that Stryker Biotech may have had with the FDA regarding OP-1 Implant, OP-1 Putty, or Calstrux are "intrinsic" to the offenses charged. Because those were Biotech's only three products, the Government's position essentially is that any interaction between Stryker Biotech and the FDA—regardless of the date such interaction took place, which employees were involved in the communication, or whether the interaction pertained in any manner to the Superseding Indictment's specific fraud allegations—is admissible. Defendants object to this overbroad interpretation of Federal Rule of Evidence 404(b). Stryker Biotech operated in a highly regulated industry, and the Government should not be allowed to color the jury's view of this case by pointing to every alleged regulatory infraction that individual FDA inspectors or employees claimed to have discovered over the years.

XII. Proof of Conspiracy to Defraud Before Admission of Co-Conspirator Statements

All of the Defendants will be challenging the admission of all co-conspirator statements under Rule 801(d)(2)(E) unless and until the Government can prove the existence of a conspiracy. Statements of co-conspirators are admissible under Rule 801(d)(2)(E) only if the trial court finds it "more likely than not that the declarant and the defendant were members of a

conspiracy . . . and that the statement was in furtherance of the conspiracy." *United States v. Petrozziello*, 548 F.2d 20, 23 (1st Cir. 1977), *abrogated on other grounds by Bourjaily v. United States*, 483 U.S. 171 (1987).

XIII. Vicarious Admissions of Biotech Employees Inadmissible Against Individual Defendants

Based on the Government's December 13, 2011 exhibit list, it appears that the Government may seek to admit out-of-court statements made by Biotech's employees (who are not named as co-conspirators) as party admissions under Rule 801(d)(2)(D). If Biotech were not a defendant in this case, then these statements would be inadmissible unless they qualified for some other exception from the hearsay rule. The Government should not be allowed to unfairly prejudice the Individual Defendants by admitting these statements simply because it has also chosen to prosecute the company for whom they worked. Accordingly, the Defendants will object to the introduction of any out-of-court statements made by Biotech's employees unless those statements qualify for a hearsay exception other than party-opponent rule.

XIV. Trial Logistics

There are certain logistical issues the Defendants wish to address at the January 4, 2012 final pretrial conference:

A. Jury Selection

The Defendants submitted a two-page proposed jury questionnaire that they believe would allow for a more efficient voir dire process. The Defendants also request the opportunity to discuss the Court's voir dire process at the January 4 pretrial conference and to discuss the number of challenges it will allow the Defendants.

B. Order of Upcoming Witnesses

The parties have agreed to provide each other with reasonable notice of the order of upcoming witnesses scheduled to testify as the trial progresses, but no specific agreement on the timing of such notice has been finalized. Defendants propose that on January 4, 2012, the Government disclose its first five witnesses and thereafter, the Government disclose its next four witnesses two days prior to calling the first of those next four witnesses. Defendants agree to follow the same protocol with respect to their witnesses, if any, starting three days before the anticipated calling of the first defense witness.

C. Use of Demonstratives

To assist the jury with the complex material at issue in this case, the Defendants may utilize several prepared demonstratives including videos, animations, and charts. Subject to the Court's preference, Defendants propose that any party seeking to use these types of demonstratives provide the other party with 24-hours advance notice and provide a copy of the demonstrative so that any objections may be heard before its proposed use.

D. Cross-Examination Procedure

In most instances, Defendants have agreed that one or two attorneys will take the primary role in the cross examination of each Government witness, although each Defendant reserves the right to cross examine any witness. The Defendants will coordinate with each other as much as possible to minimize redundancy.

E. Physical Courtroom Lay Out

Because there are a total of 18 individuals who will be "at counsel table" in this case (three AUSAs, four individual Defendants, one corporate representative and ten defense

lawyers), the Defendants would appreciate the Court's input at the January 4 conference about how the Court prefers the parties arrange seating for trial.

F. Trial Length & Scheduling of Witnesses

Given the Government's estimation that its case will last three to four weeks, Defendants have tentatively scheduled two of their experts, Dr. Jonathan Grauer and Dr. William Caton, to testify the week of February 6. Both surgeons have active surgical practices and have scheduled surgeries around these dates and anticipated travel to Boston. Although no action is needed at this stage, the Defendants may need to raise this scheduling issue with the Court depending on the pace of the trial.

Respectfully submitted,

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December 19, 2011

CERTIFICATE OF SERVICE

I, Joshua S. Levy, hereby certify that this document, filed through the ECF system, will be served electronically to the registered participants identified on the Notice of Electronic Filing ("NEF"), and that paper copies will be sent via electronic mail to those identified on the NEF as non-registered participants on December 19, 2011.

/s/ Joshua S. Levy
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